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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,273	07/15/2003	Douglas A. Collins	07959.105018 DIV	1576

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EXAMINER	
JONES, DAMERON LEVEST	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/620,273	COLLINS ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2003 and 31 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/19/03 & 10/31/0*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 7/15/03 wherein the specification was amended.

Note: Claims 1-23 are pending.

APPLICANT'S INVENTION

2. Applicant's invention is directed to compounds having the formulae as set forth in independent claims 1 and 9.

STATUTORY DOUBLE PATENTING

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

4. Claims 1-9 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 9-13 of prior U.S. Patent No. 6,004,533. This is a double patenting rejection.

5. Claims 1-8 and 14-18 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-13 of prior U.S. Patent No. 5,739,313. This is a double patenting rejection.

OBVIOUSNESS-TYPE DOUBLE PATENTING

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 9-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 5,739,313. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to compounds wherein the variable Y may be conjugated to a chelating group. The claims differ in that the instant claims disclose that the group attached to the variable Y is a chelating group while the patented claims disclose that the group attached to the variable Y *may be* a chelating group or a detectable radionuclide. Thus, a skilled practitioner in the art would be motivated to select a chelating group since the patent discloses only to choices that may be attached to the Y variable.

8. Claims 1-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,211,355. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to compounds wherein the variable Y may be conjugated to a chelating group. The claims differ in that the patented claims are directed to a method of preparing the compound and the instant claims are directed to the compound. The claims are obvious over one another because the skilled practitioner in the art would recognize that the end result is that

compounds as set forth in the instant invention are generated. Furthermore, it should be noted that independent claim 1 of the instant invention differs from the patented claims in that the group attached to the Y variable *may be* a detectable radionuclide or a chelating group. However, a skilled practitioner in the art would be motivated to select a chelating group attached to the Y variable since the instant invention discloses two possible choices for attaching to the Y variable one of which is a chelating group.

9. Claims 1-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 6-16, 23, 25, 27, 29-32, 35, 37-41, 43, 45, and 47 of U.S. Patent No. 6,613,305. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to compounds wherein the variable Y may be conjugated to a chelating group or a detectable metal. The claims differ in that the instant claims disclose that the patented invention discloses two separate formulae wherein the chelating group *may be* a detectable group which *may be* a detectable metal. The claims of the instant invention disclosed that the chelating group may be a radionuclide or paramagnetic metal.

10. Claims 1, 4-6, 14, 19, and 23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 5, 6, and 8 of U.S. Patent No. 6,096,290. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to

compounds wherein the variable Y may be conjugated to a chelating group. The claims differ in that the patented claims disclose that the Det group is a chelating group of a therapeutic radionuclide. It would have been obvious to a skilled practitioner to select a chelating group and a therapeutic radionuclide because the instant invention does not limit the radionuclide to therapeutic or detectable. In addition, a skilled practitioner would be motivated to select a chelating group attached to the Y variable because the instant invention discloses that the group attached to the Y variable may be a chelating group comprising a radionuclide or paramagnetic metal.

11. Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 and 14-23 of U.S. Patent No. 6,004,533. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to compounds wherein the variable Y may be conjugated to a chelating group. The claims differ in that the patented claims disclose that the Chel group is a chelating group which can chelate a radionuclide or a paramagnetic metal ion. It would have been obvious to a skilled practitioner to have a radionuclide or paramagnetic metal present because it is disclosed that the chelating group may chelate a radionuclide or paramagnetic metal and the instant invention discloses that the chelating agent may chelate a radionuclide or paramagnetic metal (independent claim 9, instant invention).

12. Claims 1-4, 7-10, and 13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25 and 30 of U.S. Patent No. 6,806,363. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to compounds wherein the variable Y may be conjugated to a chelating group comprising a radionuclide. The claims differ in that the patented claims disclose that the detectable moiety comprises gadolinium-157. It would have been obvious to one of ordinary skill in the art at the time the invention was made to conjugate a radionuclide to the chelating group because the instant invention is not limited to any specific radionuclide.

13. Claims 1-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 28-36, 39, and 40 of copending Application No. 09/873,142. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a chelating group optionally containing a metal. The claims differ in that independent claim 1 of 09/873,142 does not require a chelating group or a metal. However, claims 29 and 31 of 09/873,142 disclose the presence of an imaging agent bound through a chelating agent (see claim 29) and claim 31 disclose the presents of a radionuclide or paramagnetic metal. Thus, a skilled practitioner in the art would recognize that the requirements of independent claims 1 and 9 of the instant invention are fulfilled .

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 1-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 28-36 of copending Application No. 09/873,164. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a chelating group optionally containing a metal. The claims differ in that independent claim 1 of 09/873,164 does not require a chelating group or a metal. However, claims 29 and 31 of 09/873,164 disclose the presence of an imaging agent bound through a chelating moiety (see claim 29) and claim 31 disclose the presents of a radionuclide or paramagnetic metal. Thus, a skilled practitioner in the art would recognize that the requirements of independent claims 1 and 9 of the instant invention are fulfilled .

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 1-4, 9-13, and 19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 15, 16, and 18 of copending Application No. 10/027,593. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a chelating group optionally containing a metal. The claims differ

in that independent claim 1 of 10/027,593 does not require a chelating group or a metal. However, claim 3 of 10/027,593 discloses the presence of a variable T which a detectable and/or therapeutic radionuclide. Thus, a skilled practitioner in the art would recognize that the requirements of independent claims 1 and 9 of the instant invention are fulfilled since a radionuclide (e.g., metal) may be present. In addition, a skilled practitioner would recognize that a chelating moiety may be present since in claim 1, the variable T is described as optionally being bound through a chelating moiety. In addition, a skilled practitioner in the art would recognize that a proliferative disorder encompasses tumors. Thus, both inventions may be used in tumor treatment.
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claim 9 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/028,857. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims optionally have a metal present. The claims differ in that independent claim 1 of 09/873,164 does not require a chelating group or a metal. Thus, the skilled practitioner in the art would recognize that the inventions contain overlapping subject matter.
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claims 1-3, 9, and 19-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 24, 29, 44, 54, 56, 57, 59, 70, 73, and 74 of copending Application No. 10/777,820. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a radionuclide or chelator-radionuclide combination. The claims differ in that independent claim 1 of 10/777,820 does not require a radionuclide or chelate-radionuclide combination. However, it would be obvious to one of ordinary skill in the art to use a radionuclide or chelate-radionuclide combination because claims 30, 54, 56, 57 of 10/777,820 disclose the presence of a chelator-radionuclide combination or radionuclide.. Thus, a skilled practitioner in the art would recognize that the requirements of independent claims 1 and 9 of the instant invention are fulfilled

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

COMMENTS/NOTES

18. It should be noted that no prior art has been cited against the claims. However, Applicant MUST address and overcome the double patenting rejections above. In particular, the claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious compounds as set forth in independent claims 1 and 9. The closest art is that which is cited in the double patenting rejections above.

19. In order to clarify claim 19, Applicant is respectfully requested to replace 'an amount' with 'an effective amount' to indicate that the amount of compound administered to subject is dependent upon weight, age, etc. of the subject. Hence, the dosage administered to a subject may various depending upon the subjects characteristics..

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

D. L. Jones
Primary Examiner
Art Unit 1616

February 4, 2005